

### **REMARKS**

Applicants respectfully request the Examiner to reconsider the present application in view of the foregoing amendments to the claims and the following remarks.

#### ***Status of the Claims***

After entry of the instant Amendment, claims 1-12 are pending in the present application. The Office Action is non-final. Claim 3 has been amended to make it depend only from claim 2 without prejudice to or disclaimer of the subject matter contained therein. New claims 7-12 are based on the disclosure in the specification at page 6, lines 32-33, and Examples 1 and 2 at pages 8-10 of the specification. No new matter has been added by way of the amendments.

Based upon the above considerations, entry of the present Amendment is respectfully requested.

#### ***Information Disclosure Statements***

The Examiner indicated that item BB (JP-2003-518379-T) listed in the Information Disclosure Statement filed July 13, 2009, was not considered as Applicants did not provide an English translation of the document, nor did Applicants provide an English abstract. Applicants provided the English abstract for WO 01/48148 A1, which is the published PCT application that corresponds to JP-2003-518379-T.

#### ***Priority***

Applicants have not yet received a PCT/IB/304 form from the International Bureau. However, the WIPO website shows that the International Bureau received a certified copy of JP-2003-283703 (foreign priority application filed in Japan on July 31, 2003) on September 16, 2004. Thus, the requirements under PCT Rule 17.1(b) have been satisfied. A copy of the front page of the certified copy of JP-2003-283703 is attached for the Examiner's review.

Applicants are also filing an English translation of JP-2003-283703 herewith for the Examiner's inspection.

***Issue Under 35 U.S.C. § 112, Second Paragraph***

Claim 3 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. It is stated in the Office Action that there is insufficient antecedent basis in claim 1 for the term “joint surface” recited in claim 3. Applicants have amended claim 3 to depend only from claim 2 (which provides antecedent basis for the term), thereby obviating the rejection of claim 3 under 35 U.S.C. § 112, second paragraph. Applicants respectfully request that the rejection of claim 3 as being indefinite be withdrawn.

***Issue Under 35 U.S.C. § 102(b)***

Claims 1 and 4-6 are rejected under 35 U.S.C. § 102(b) as being anticipated by Britt et al., “Autogenous tissue-engineered cartilage: evaluation as an implant material,” Arch Otolaryngol Head Neck Surg, 1998, Vol. 124, No. 6, pp. 671-677 (hereinafter “Britt”). Applicants respectfully traverse this rejection.

Claims 2-6 are rejected under 35 U.S.C. § 102(b) as being anticipated by van Susante et al., “Linkage of chondroitin-sulfate to type I collagen scaffolds stimulates the bioactivity of seeded chondrocytes *in vitro*,” Biomaterials, 2001, Vol. 22, No. 17, pp. 2359-2369 (hereinafter “van Susante”). Applicants also respectfully traverse this rejection.

Neither Britt nor van Susante teaches or suggests “adhering cell masses onto the surface of a carrier” shaped into a desired form and culturing the cell masses, as in the claimed invention. The “cell masses” recited in independent claims 1 and 2 are cell aggregation masses or spheroids formed by cells adhering to each other. *See* page 5, lines 2-4 of the specification.

Britt and van Susante only disclose cells (not cell masses) adhered to the surface of a carrier, which are cultured. Britt at page 673, under the heading “CHONDROCYTE SEEDING OF POLYMER TEMPLATES,” discloses that a volume of isolated chondrocyte solution was applied to the polymer template in an effort to achieve a cell concentration of 1 to  $2 \times 10^7/\text{cm}^3$  of template material. van Susante at page 2361, under the heading “2.3. Chondrocyte isolation and seeding,” discloses that sponges were seeded with 100  $\mu\text{l}$  of a cell suspension containing 850,000 chondrocytes, followed by gentle centrifugation of the entire plate (3 min, 600g), which revealed

optimal penetration of the cells into the pores at the air-side of the sponges. All of these disclosures by Britt and van Susante teach that cells (not cell masses) are adhered to the surface of a carrier and cultured.

Thus, Britt and van Susante do not disclose each and every element of the claimed invention, and Applicants respectfully request that the rejection of claims 1-6 as being anticipated by the cited art be withdrawn.

### CONCLUSION

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Stephanie A. Wardwell Reg. No. 48,025, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Dated: December 3, 2009

Respectfully submitted,

By

  
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Attachment: English Translation Of JP-2003-283703